

PATENT
ATTORNEY DOCKET NO.: UCSD1130-1

Applicants: Fahey et al.

Application No.: 09/530,370

Filed: July 6, 2000

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REMARKS

Claims 1-40 and 42-50 were pending prior to this Response, with claims 12-39 and 43-45 being withdrawn due to a restriction requirement. By the present communication, claims 4, 12-39, 43-45 46 and 47 have been canceled without prejudice and claims 1, 7, 9-11 and 48 have been amended as shown in attached Exhibit A to define Applicants' invention with greater particularity. No new matter has been added, the amended claim language being fully supported by the Specification and original claims. Accordingly, claims 1-3, 9-11, 40, 42 and 48-50 are pending and under consideration in this application.

The Rejection Under 35 U.S.C. § 112, First Paragraph

Applicants respectfully traverse the rejection of claims 1-8 and 46-50 under 35 U.S.C. § 112, First Paragraph, for lack of enablement on the grounds that the Specification allegedly fails to teach how to distinguish mycothiol from any and all other thiol-containing compounds using only the thiol-selective "reagent". In support of the rejection, the Examiner asserts that step b of claim 1 requires one only to have a reaction of the reagent with a thiol-containing component of the sample, making it impossible to distinguish between actinomycetes and any other microorganism or cell containing thiols (Office Action, page 5). Claims 46 and 47 have been canceled without prejudice, rendering the rejection moot as to claims 46 and 47.

Moreover, the invention method for detecting actinomycetes in a sample, as defined by amended claim 1, requires (a) sequentially incubating with the sample a thiol-selective reagent to

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produce thiol derivatives, a purified antibody that specifically binds to a mycothiol derivative or a thiol-containing mycothiol component derivative, and a reagent for detecting binding of the antibody to sample components for a time sufficient for said antibody to react with said mycothiol derivative or said thiol-containing mycothiol component derivative; and

(b) detecting binding of said antibody with said mycothiol derivative or a thiol-containing mycothiol component derivative, wherein the binding indicates presence of a member of the taxa actinomycetes in the sample. Thus, in the presently claimed invention methods, the thiol-specific agent derivatizes all thiols in the sample components, but the invention antibody (the primary antibody in the assay) binds only to derivatives in the sample that contain mycothiol or a thiol-containing mycothiol component. Thus, any detection reagent can be used that recognizes binding of the antibody to sample components, including a secondary antibody. Applicants have clarified this by the amendment to claim 1 requiring that the antibody used in the detection methods binds *specifically* to the mycothiol derivative and to thiol-containing mycothiol component derivatives formed by incubation of the sample with the thiol-selective reagent. Binding of the thiol-selective reagent to any additional thiols in the sample merely serves as a blocking agent to counteract the high reactivity of thiols.

Therefore, Applicants respectfully submit that the invention method will not produce false positives by detecting *all* thiol-containing component in the sample. Accordingly, Applicants respectfully submit that the amendment to claim 1 to clarify the assay method avoids encompassing the case wherein it is the reagent alone that is responsible for selecting out the mycothiol or thiol-containing mycothiol components in the sample.

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Applicants also traverse the rejection of claims 5, 10, 40, and 42 under 35 U.S.C. § 112, First Paragraph, for containing subject matter which was allegedly not described in the specification in such a way as to reasonably convey to those of skill in the art that the inventors has possession of the claimed subject matter. Specifically, the Examiner asserts that the specification provides only examples of one polyclonal antibody and, hence, does not meet the description requirements of Section 112, First Paragraph, with respect to the monoclonal antibodies recited in claims 5 and 10 and encompassed by claims 40 and 42 (Office Action, pages 5-6).

Applicants disagree with the Examiner's assertions because the Specification contains a complete description of the preparation of polyclonal antibody purified by affinity chromatography from sera of rabbits immunized with KLH-BM-SM conjugates. IgG fractions were isolated from rabbit sera by ammonium sulfate precipitation in a two-step process as described in detail in Example 3. In addition, the Specification contains detailed description of the well-known procedures by which monoclonal antibodies are prepared *once an animal that produces specific antibodies has been obtained*. Both production of monoclonal antibodies (Specification, page 12) and methods for *in vitro* and *in vivo* multiplication of monoclonal antibodies (Specification, page 13) are further described. Applicants respectfully submit that, where preparation of the antigen and of specific polyclonal antibodies using the antigen has been shown, as in the instant case, those of skill in the art would not require an inventor to describe production of a monoclonal antibody to "reasonably convey" that the inventor is in possession of the claimed invention (i.e., the conception and constructive reduction to practice) of such monoclonal antibodies. Accordingly, Applicants respectfully submit that claims 5, 10, 40 and 42

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meet all requirement under 35 U.S.C. § 112, First Paragraph, and reconsideration and withdrawal of the rejection are respectfully requested.

The Rejection under 35 U.S.C. § 101

Applicants respectfully traverse the rejection of claims 9-11 under 35 U.S.C. § 101 as allegedly containing non-patentable subject matter because the claims read on a product of nature. To overcome the rejection, claims 9-11 have been amended by the present communication to require that the antibody is an "isolated antibody", thus overcoming the grounds for the rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 9-11 under 35 U.S.C. § 101.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' representative, Lisa A. Haile, J.D., Ph.D., can be reached at (858) 677-1456.

Respectfully submitted,

Date: February 14, 2003


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Enclosure: Exhibit A



ATTORNEY DOCKET NO.: UCSD 10-1

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Exhibit A: Page 1

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EXHIBIT A

Version with Markings to Show Changes Made

Please cancel claims 4, 12-39, 43-45, 46 and 47 without prejudice.

Please amend claims 1, 7, 9-11, and 48 as follows:

1. (Twice Amended) A method of detecting a member of the taxa actinomycetes in a sample, comprising:

(a) sequentially incubating with the sample a thiol-selective reagent to produce thiol derivatives, [and] a purified antibody that specifically binds to a mycothiol derivative or a thiol-containing mycothiol component [with a sample] derivative, and a reagent for detecting binding of the antibody to sample components for a time sufficient for said [reagent or said] antibody to react with said mycothiol derivative or said thiol-containing mycothiol component derivative; and

(b) detecting [reaction of said reagent or said] binding of the antibody with said mycothiol derivative or [a] said thiol-containing mycothiol component derivative,

[thereby indicating the] wherein the binding indicates presence of a member of the taxa actinomycetes in the sample.

7. (Amended) The method of claim 1, further comprising

(c) quantitating said mycothiol or said thiol-containing mycothiol component in the sample.

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9. (Twice Amended) An isolated antibody which binds specifically to a maleimidyl derivative of mycothiol or of a thiol-containing mycothiol component.

10. (Amended) The isolated antibody of claim 9, wherein the antibody is monoclonal.

11. (Amended) The isolated antibody of claim 9, wherein the antibody is polyclonal.

48. (Amended) The method of claim [47] 1, wherein said detection reagent is directly labeled with a label.